In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 19-1703V

FIDENCIO VELASQUEZ,	*	
	*	Chief Special Master Corcoran
Petitioner,	*	Filed: January 31, 2024
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Scot Tyler Scheuerman, Scheuerman Law Firm PLLC, San Antonio, TX, for Petitioner.

Zoe Wade, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On November 1, 2019, Fidencio Velasquez filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Program").[2] ECF No. 1. Petitioner alleges that an influenza ("flu") vaccine he received on November 1, 2016, caused him to incur Guillain-Barré syndrome ("GBS"). *Id.* Although the matter was originally assigned to the "Special Processing Unit" ("SPU"), since it appeared to assert the kind of claim often easily settled, fact issues pertaining to the nature of injury as well as its timing resulted in the claim's transfer to my regular docket.

[1] As provided by 42 U.S.C. § 300aa-12(d)(4)(B), the parties may object to the published Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Decision will be available to the public in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

The parties have submitted expert reports and offered briefs so that the matter can be resolved via ruling on the record. *See* Petitioner's Motion, dated June 12, 2023 (ECF No. 54) ("Mot."); Respondent's Opposition, dated September 18, 2023 (ECF No. 61) ("Opp."). For the reasons stated in more detail below, I deny compensation.

I. Fact History

Mr. Velasquez was fifty-two years old at the time of vaccination, and was then employed by a golf course in Eagle Pass, TX. Ex. 2 at 14; Ex. 7 at 1, ¶4. His medical history was significant for diabetes and hypertension, and he received a number of medications in treatment of these pre-vaccination conditions. Certified Medical Records - Hector Trevino, MD, filed on June 12, 2020 (ECF No. 21-3) at 16–78 (handwritten records from 2011-16 noting diabetes, hypertension, and cholesterol medications).

Even more importantly, the record establishes that Petitioner sought treatment in the days immediately prior to vaccination for a gastrointestinal complaint. Specifically, on Friday, October 28, 2016 (four days before receiving the flu vaccine at issue), he saw his primary care physician ("PCP"), Hector Trevino, M.D., reporting abdominal pain and fatigue starting the day prior, as well as two days of diarrhea and fever. Ex. 2 at 19. He was diagnosed with "[g]astroenteritis" and prescribed an antibiotic. *Id*. Around this time he also underwent blood testing in connection with his previously-diagnosed diabetes. Ex. 2 at 18.

Vaccination and Neurologic Symptoms Onset

Petitioner received the flu vaccine at issue in this case on Tuesday, November 1, 2016, in connection with a follow-up visit to Dr. Trevino to discuss the results of his lab workup for his diabetes (which was noted to be poorly controlled). Ex. 2 at 14, 16. (Indeed—the results of the testing lead to a treater determination to increase Petitioner's insulin dose (*Id.* at 16)). Petitioner at this time express a new complaint of back pain, and Dr. Trevino's exam noted back pain and right leg weakness, but without pain on palpation. *Id.* at 16.

Three days later (November 4th), Petitioner went to Fort Duncan Medical Center Emergency Department ("ED"), reporting that he "has been not feeling well for approximately one week." Ex. 3 at 9. (If correct, this would place onset *prior* to vaccination). The history taken at this time memorializes Mr. Velasquez's statement that he was experiencing headaches and paresthesias, plus lower extremity weakness, and that he believed his prior vaccination could be the cause. *Id.* at 9, 88. The ER exam was normal, however, and also normal from a neurologic perspective, and other testing (X-ray, CT scan, and lab work) yielded normal results as well. *Id.* at 10–12. Mr. Velasquez was discharged that same day from the ED in stable condition and advised to follow up with his PCP. *Id*. at 12–13.

Then, on the evening of November 6, 2016 (now five days post-vaccination), Mr. Velasquez was admitted to the ED at Baptist Medical Center based on his reports of "[p]rogressive weakness since flu vaccine, reporting generalized weakness, unable to open right hand well." Ex. 4 at 52. Petitioner claimed an onset of hand-related weakness to have occurred immediately before arrival at the hospital, but that otherwise he had been experiencing constant, worsening symptoms impacting his ability to walk (due to weakness in his legs) for five days, or since the date of vaccination. *Id.* Testing performed at this time revealed high blood pressure and blood sugar levels, although otherwise the exams again produced normal findings. *Id.* at 53, 55. Petitioner was held overnight but then discharged—and he was now proposed to have a peripheral neuropathy given his reported history of leg weakness. *Id.* at 67–74.

Follow-Up Treatment After Fall 2016 Onset

After this second ED encounter from early November 2016, Petitioner saw Dr. Trevino again. Ex. 2 at 13. Petitioner now provided a more precise date for onset of his symptoms, informing Dr. Trevino that he had started to feel right hand weakness on November 3rd—two days after going bowling (and getting vaccinated the same day). *Id.* The physical medical record from this visit includes a handwritten timeline of these events. *Id.*

On exam, Petitioner displayed left and right hand weakness, and he could not extend the fingers on his left hand. Ex. 2 at 13. He also was experiencing arm and leg weakness, but reported improvement in his leg strength. *Id*. Dr. Trevino assessed Mr. Velasquez at this time with GBS, "most likely improving." *Id.* This is the first record in which GBS was proposed as a diagnostic explanation for Petitioner's medical complaints.

Petitioner saw Dr. Trevino another time on November 10, 2016, for follow-up treatment for his limb weakness. Ex. 2 at 12. He was noted to be displaying strength improvement, and was now able to tiptoe, but still unable to heel walk. *Id.* Dr. Trevino again opined that GBS was the "most likely" diagnosis, and noted "consider adverse [reaction] to flu shot." *Id.* Petitioner was referred to neurology, and informed he would likely need to limit work for several months. *Id.* Days after this visit, Dr. Trevino's office reached out to the vaccine manufacturer to report Petitioner's purported vaccine reaction. Ex. 2 at 11.

Petitioner thereafter had his first neurologic evaluation in mid-November 2016, with Dr. Fernando Sanchez, at the Fernando Sanchez Clinical Neurophysiology Center. Ex. 5 at 17–18. Petitioner's reported onset was now *three* days post-vaccination (or November 4th), and he described the weakness that he had previously reported in connection with his ED visits. *Id.* at 17. On exam, petitioner's reflexes were normal, and displayed moderate quadriceps strength, but had bilateral wrist and foot drop. *Id*. Based solely on this exam and a normal MRI result, Dr. Sanchez

diagnosed petitioner with "GBS, postvaccinal, motor axonal variant," and noted the need to perform an EMG.[3] *Id.* at 17, 18.

The planned EMG of the left upper and lower extremities occurred on December 2, 2016. Ex. 5 at 16, 40–44. Its results were interpreted to reveal the presence of an "[a]cute, predominantly axonal motor polyneuropathy," with "motor axonal loss and active denervation in distal [more than] proximal limb muscles." *Id.* A few days later, Petitioner saw Dr. Trevino again, who observed some improvements but assessed Mr. Velasquez with "GBS post[-]vaccinal motor axonal variant," which he expected to improve in three to six weeks. Ex. 2 at 10. Some additional progress was also noted later that month in a subsequent visit to Dr. Trevino, although it was expected that monitoring would be necessary to evaluate when Petitioner's strength had sufficiently returned to permit him to work again. *Id.* at 9.

2017 Treatment and Subsequent Medical History

On January 16, 2017, Petitioner saw Dr. Trevino, reporting ongoing issues with the use of his hands and legs. Ex. 2 at 8. His diabetes also remained poorly controlled. *Id.* Dr. Trevino supplied him with work absence authorizations given his continued weakness. *Id.* at 7. That same month, Petitioner also went back to Dr. Sanchez for further neurologic treatment. Ex. 5 at 15. He displayed mild improvement but continued to experience hand grip and leg weakness. *Id.* Dr. Sanchez projected sequelae from GBS to persist for several additional months, but also proposed that Petitioner could soon return to work (albeit with some activity restrictions). *Id.* Petitioner attempted to do so at the end of January, but found his ongoing weakness impeded his ability to perform tasks at work. Ex. 2 at 5.

For the remainder of 2017, Petitioner reported lingering hand grip issues and limb weakness, albeit with some moderate improvement as time passed. *See,* e.g., Ex. 2 at 4 (July 2017 visit with Dr. Trevino); Ex. 5 at 31 (August 2017 visit to new neurologist); Ex. 2 at 2 (October 2017 visit to Dr. Trevino); Ex. 5 at 13 (November 2017 follow-up visit to Dr. Sanchez). The same general symptoms were also reported the following year. Ex. 5 at 12 (June 2018 visit to Dr. Sanchez, reporting pain, bilateral limb weakness in the upper and lower extremities).

In later 2018 into 2019, Petitioner experienced decreased muscle strength and right-sided weakness. Ex. 5 at 11 (December 2018 visit to Dr. Sanchez reporting hand tremor and bilateral weakness more notable on the right side of the body); Ex. 5 at 10 (June 2019 visit to Dr. Sanchez reporting right-sided fatigue and weakness). Petitioner stopped treatment for his issues after June

[3] An "EMG," or electromyogram, is the record from an electromyography, "an electrodiagnostic technique for recording the extracellular activity of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation." *Electromyogram*, Dorland's Medical Dictionary Online (https://www.dorlandsonline.com/dorland/definition?id=15852) and *Electromyography*, Dorland's Medical Dictionary Online (https://www.dorlandsonline.com/dorland/definition?id=15854&searchterm=electromyography)

2019, but states in his affidavit that he still feels weakness on a daily basis. Ex. 7 at 2. Petitioner was able to resume part-time work in September 2019, and then full-time work in January 2020. *Id.*

II. Expert Reports/Treater Statements

A. *Petitioner's Expert – David M. Simpson, M.D.*

Dr. Simpson, a neurologist, prepared two written reports for the Petitioner. Report, dated April 5, 2022, filed as Ex. 15 (ECF No. 43-2) ("First Simpson Rep."); Report, dated June 3, 2023, filed as Ex. 18 (ECF No. 53-3) ("Second Simpson Rep.").

Dr. Simpson is a Professor of Neurology and the Director of the Neuromuscular Division and Clinical Neurophysiology Laboratories at the Icahn School of Medicine at Mount Sinai, where he has worked as an Attending Neurologist since 1984. Curriculum Vitae of David Simpson, MD, FAAN, filed on April 5, 2022 (ECF No. 43-3) ("Simpson CV"). He received his medical degree from SUNY at Buffalo School of Medicine, and underwent residency and fellowship training at Cornell University Medical Center and Massachusetts General Hospital. Simpson CV at 1. He is certified by the National Board of Medical Examiners, the American Board of Psychiatry and Neurology with subspecialties in Clinical Neurophysiology and Neuromuscular Medicine, and the American Board of Neuromuscular and Electrodiagnostic Medicine. *Id.* He has been published extensively on the subject of central and peripheral neurological disorders. *Id*. at 22–36.

First Report

Dr. Simpson's initial report responded to the opinion submitted by Respondent's expert, Dr. Mark Bromberg. He began by detailing the materials he reviewed, then provided his own summary of Petitioner's relevant medical history. *See* First Simpson Rep. at 2–4. He then noted the medical and scientific support for an association between the flu vaccine and two subvariants of GBS—acute inflammatory demyelinating polyneuropathy ("AIDP") or chronic inflammatory demyelinating polyneuropathy ("CIDP"). *Id.* at 4–5. Because this Decision does not turn on the nature of the injury, this part of Dr. Simpson's report does not merit much discussion. However, in this section, Dr. Simpson did note that "numerous biologic mechanisms" had been proposed for how a vaccine could result in GBS, including an autoimmune cross-reaction due to molecular mimicry—a process that would inherently implicate the secondary, adaptive immune response. *Id.* at 4, 5.

Mr. Velasquez's GBS, Dr. Simpson maintained, was more likely that not caused by his preceding vaccination. First Simpson Rep. at 9. To support this opinion, Dr. Simpson analyzed both the post-vaccination timeframe for onset plus some of the points made about Petitioner's history by his treaters, Drs. Trevino and Sanchez. He deemed onset to have occurred three days

after vaccination, relying on Petitioner's affidavit (even though contemporaneous records suggested an earlier onset—or even one predating vaccination). *Id.* at 5. Such an onset was consistent with not only existing science, but the Table as well. *Id.* at 5–6. In fact, he maintained, the "true range of attributable risk" was *greater,* on both ends, than the Table's 3-42 day period. *Id.* at 5, 6–7; Y. Park et al., *Clinical Features of Postvaccination Guillain-Barré Syndrome (GBS) in Korea*, 32 J. Korean Med. Sci. 1154, 1156 (2017) ("Park")[4]; L.B. Schonberger et al., *Guillain-Barre Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976-1977*, 110 Am. J. Epidemiol. 105, 123 (1979) ("Schonberger").

Dr. Simpson then turned to evidence from Petitioner's history he deemed supportive of his opinion. He noted "severe generalized weakness" observed by Petitioner's treaters as a primary criterion of GBS. First Simpson Rep. at 8. In addition, the EMG testing performed on Petitioner in 2016 revealed "motor axonal neuropathy," consistent with a GBS variant *other* than AIDP or CIDP—acute motor axonal neuropathy, or "AMAN." *Id.* He deemed the AMAN variant also associated with the flu vaccine, citing literature for this contention. A. Shaikh et al., *Atypical Forms of Guillain-Barré Syndrome and H1N1-influenza Vaccination*, 30 Vaccine 3251, 3254 (2012). And a second EMG (albeit one performed in late summer 2018—almost two years after the vaccination event) was consistent with "poorly recovered GBS or CIDP," since there was evidence of axonal degeneration. First Simpson Rep. at 8.

The possibility that Petitioner's GBS was associated with his pre-vaccination gastroenteritis infection was dismissed by Dr. Simpson. He acknowledged that the record clearly established Petitioner had received treatment for gastrointestinal symptoms, and that they could have been caused by a *Campylobacter jejuni* bacterial infection. First Simpson Rep. at 8. But he purported that reliable medical literature suggested onset of GBS associated with such a specific bacterial infection occurred no sooner than a week after vaccination—meaning that Petitioner's onset was "too early" to have had this as its cause. *Id*; B. Allos, *Association Between Campylobacter Infection and Guillain-Barre´ Syndrome*, 176 J. Infect. Dis. 125 (1997).

In addition (and as noted below), Dr. Trevino had proposed that, in light of Petitioner's subsequent medical history, these gastrointestinal symptoms might be better now understood to have been reflective of gall bladder disease. First Simpson Rep. at 8. And it was not clear at all whether Petitioner's symptoms were otherwise caused by a viral infection, or even some other kind of bacterial infection not associated with GBS (unlike *C. jejuni*). *Id.* at 8–9. Petitioner had never been tested to see if he possessed a *C. jejuni* infection, and it was now far too late to do so. And no other possible explanatory cause existed for why Petitioner had developed any form of GBS. *Id.* at 9.

[4] Petitioner never filed any of the medical literature referenced in Dr. Simpson's report. Accordingly, there are no record citations to them, and their contents could not be reviewed (although I am familiar with some of the items referenced, based on my experience adjudicating comparable claims).

Second Report

Dr Simpson prepared a brief supplemental report addressing some of Dr. Bromberg's criticisms of his initial opinion. He noted that there was no disagreement as to the fact that Petitioner had experienced some form of peripheral neuropathy; the primary dispute between the neurologic non-treating experts was what the electrodiagnostic testing results revealed about the specific character of the neuropathy. Second Simpson Rep. at 1–2. Based on his own review of the results, Dr. Simpson deemed Dr. Bromberg's criticisms about inaccuracies in the EMG study not well-founded, relying as well on his interpretive views that certain findings were atypical for GBS. *Id.* In the end, Dr. Simpson deemed the results to be fully consistent with the AMAN form of GBS—observing that not only had Dr. Sanchez so concluded, but also that Dr. Bromberg *himself* had allowed this to be likely. *Id.* at 2.

Next, Dr. Simpson addressed Dr. Bromberg's contentions regarding alternative causes for Mr. Velasquez's GBS. First, he denied that Petitioner's presentation was reflective of a diabetic neuropathy, arguing that Petitioner had no neurologic symptoms before vaccination, and otherwise that his clinical features and EMG/NSC testing were "entirely consistent with GBS" as opposed to a different form of neuropathy. Second Simpson Rep. at 2. Second, he reiterated prior points about why Petitioner's GBS was unlikely the product of a *C. jejuni* infection, since the onset in this case was too long, and given his speculation that Petitioner's 2016 symptoms were more likely reflective of gall bladder disease. *Id.* at 3. Dr. Simpson concluded with another overview of molecular mimicry as a likely, vaccine-induced mechanism for GBS. He emphasized the fact that there existed substantial support in the medical and scientific literature for a vaccine association. *Id.*

C. *Treating Expert Opinions*

1. Dr. Hector Trevino – As the medical record discussed above demonstrates, Dr. Trevino was Petitioner's PCP, treating him contemporaneously with both his vaccination, intercurrent gastrointestinal illness, and then when neurologic symptoms first manifested. He has offered a brief affidavit addressing certain fact issues in this case. *See* Affidavit, dated June 23, 2021, filed as Ex. 12 (ECF No. 32-2) ("Trevino Aff.").

Dr. Trevino's affidavit begins with a reiteration of the treatment for perceived gastroenteritis that he provided Petitioner immediately before the November 1, 2016 vaccination. Trevino Aff. at 1. He proposed that because Petitioner was prescribed a seven-day course of antibiotics, he should have been clear of the bacteria at the end of the course. *Id.* But because the records revealed Petitioner was still receiving the medication as of November 6th, it was likely the bacteria responsible (which he acknowledged was often *C. jejuni* in cases of gastroenteritis) remained present. (He later noted that it could not be ascertained from the record with certainty whether Petitioner's gastroenteritis was viral or bacterial in origin. *Id.* at 2).

However, Dr. Trevino added, medical literature suggested that GBS attributable to *C. jejuni* typically had a somewhat-longer timeframe onset of one to three weeks. Trevino Aff. at 2; Irving Nachamkin et al., *Campylobacter Species and Guillain-Barré Syndrome*, 11 Clin. Microbiol. Rev. 555, 556 (1998).[5] Thus, if Petitioner's GBS were due to a *C. jejuni* wild infection, it should not have manifested until November 11th at the earliest. Trevino Aff. at 2. This left, in Dr. Trevino's opinion, the vaccine as the only likely cause. *Id.* He also added that although Petitioner had complained of back problems on November 1st, he had not deemed them at any later time to be associated with GBS. *Id.*

Besides these opinions, Dr. Trevino also offered a statement about the import of certain treatment findings made in the spring of 2021 (and hence nearly four and a half years post-vaccination). Trevino Aff. at 2, 3-6; *see also* Ex. 14 at 6-30. He noted that the operative report associated with the cholecystectomy (gallbladder removal) procedure performed on Petitioner in March 2021 supported the conclusion that Petitioner had actually been suffering from gallbladder disease—the symptoms of which he purported "overlap" with those of gastroenteritis. Trevino Aff. at 2. Thus, the very diagnosis of gastroenteritis was called into question, as the symptoms Petitioner displayed in October 2016 could have reflected "a flair up of his chronic gallbladder disease." *Id.*

2. Dr. Fernando Sanchez – Dr. Sanchez, Petitioner's neurologist from November 2016 to June 2019, prepared a brief affidavit in support of the claim. *See* Affidavit, dated June 25, 2021, filed as Ex. 13 (ECF No. 32-3) ("Sanchez Aff."). He indicates therein that the records of Petitioner's treatment with Dr. Trevino revealed a pre-vaccination diagnosis of a bacterial gastroenteritis (a conclusion he reached based on the medicine then prescribed), and that onset seemed to have begun November 3, 2016 (hence two days after Petitioner received the flu vaccine). Sanchez Aff. at 1.

Dr. Sanchez then opined that the flu vaccine had caused Petitioner's GBS. Sanchez Aff. at 1. In so opining, he acknowledged that *C. jejuni* is "[t]he most common cause" for the kind of gastroenteritis Petitioner experienced, and that the same infection is associated with GBS. *Id.* Nevertheless, onset for a bacterially-caused GBS would occur no sooner than seven to ten days post-infection—whereas in this case Petitioner's GBS began far sooner. *Id.* at 2. Because of this, and because there were no other explanations evident from the record that could account for Petitioner's injury, the vaccine was left as most likely causal. *Id.*

[5] Petitioner has not filed any of the medical literature referenced by Dr. Trevino. Accordingly, there are no record citations.

C. *Respondent's Expert – Mark B. Bromberg, M.D.*

Dr. Bromberg prepared three expert reports in this case. Report, dated November 29, 2021, filed as Ex. A (ECF No. 39-1) ("First Bromberg Rep."); Report, dated October 12, 2022, filed as Ex. K (ECF No. 50-1) ("Second Bromberg Rep."); Report, dated August 8, 2023, filed as Ex. L (ECF No. 59-1) ("Third Bromberg Rep.").

Dr. Bromberg is an academic neurologist and professor at the University of Utah. Curriculum Vitae of Mark B Bromberg, M.D., filed November 29, 2021 (ECF No. 39-2) ("Bromberg CV"). He received his Ph.D. in neurology from the University of Vermont, and his medical degree from the University of Michigan. Bromberg CV at 1. In addition to being a professor, he sees patients in a general neurology clinic. *Id*. at 2. He has published many neurology articles, and authored a textbook on peripheral neuropathies and the diagnosis of small fiber neuropathies. *Id.* at 19–37. He is certified by the American Board of Psychiatry and Neurology and the American Board of Electrodiagnostic Medicine, and holds medical licenses in Utah and Wyoming. *Id.* at 6.

First Report

Dr. Bromberg's initial report reacted to the two affidavits from Petitioner's treaters, Drs. Trevino and Sanchez. He began by summarizing Petitioner's medical history, emphasizing certain aspects of it. First Bromberg Rep. at 1–6. He noted, for example, Petitioner's pre-vaccination history of diabetes and the associated high A1c readings.[6] *Id.* at 2. He highlighted the electrodiagnostic testing performed on Petitioner in December 2016, which confirmed the existence (in Dr. Sanchez's view) of a "predominantly axonal motor neuropathy" (*Id.* at 2), but which did not also reveal significant demyelination or sensory nerve loss. *Id.* at 3, 7.[7] And he observed ongoing deficiencies into late 2017 and even 2018. *Id.* at 5–6.

Dr. Bromberg next provided his understanding of GBS as a clinical diagnosis. He noted that the term includes "a spectrum of disorders," from an acute form to the AMAN version apparently at issue in this case. First Bromberg Rep. at 6. He found reasons to question whether AMAN was the best diagnostic descriptor for Petitioner's injury, however. Several indicia set forth

[6] *See Hennessey v. Sec'y of Health & Hum. Servs.,* 91 Fed. Cl. 126, 131 (2010) for explanation of the difference between blood glucose levels and A1c: "Because hemoglobin A1c has a known finite life span, the percentage of hemoglobin A1c at any given time can be used to determine the average level of blood glucose for a period prior to the test. Unlike spot readings of current blood glucose levels, a hemoglobin A1c test result changes very slowly and represents an average of blood glucose levels over the previous three to four months. Thus, this one test serves the same function as multiple spot readings of the constantly fluctuating glucose levels."

[7] Dr. Bromberg did question the accuracy of this testing, however, noting several findings that were either consistent with error in how the testing was performed, or reflected other potential "operator technical difficulties"—leading him to opine that the test results had to be "force-fitted into a diagnosis of AMAN." First Bromberg Rep. at 7.

in widely-accepted medical community criteria (preservation of tendon reflexes or asymmetry of weakness) were absent, for example. *Id.* at 7. In addition, the lower limb areflexia common to GBS was never observed in Mr. Velasquez's case. *Id,* S. Kuwabara et al., *Hyperreflexia in Guillain-Barré Syndrome: Relation With Acute Motor Axonal Neuropathy and Anti-GM1 Antibody*, 67 J. Neurol. Neurosurg. Psychiatry 180, 181 (1999), filed as Exhibit K (ECF No. 39-5). The fact that Petitioner displayed plantar issues, or even hyperreflexia, were also not consistent with GBS. First Bromberg Rep. at 7. And the same was true for the predominantly upper limb/hand and wrist weakness without reduced or absent reflexes were also not common to the AMAN GBS variant. *Id.* Nevertheless, Dr. Bromberg allowed that Petitioner's overall presentation was "possibly" reflective of an atypical AMAN presentation. *Id.*

But even if GBS were a reasonable diagnosis, Dr. Bromberg denied that Petitioner's vaccination could explain it. Rather, it was more likely the product of the pre-vaccination gastrointestinal infection Petitioner had experienced. Reliable literature suggested that in the majority of cases, GBS was attributable to some form of preexisting infection. First Bromberg Rep. at 8; Penina Haber et al., *Vaccines and Guillain-Barré Syndrome*, 32 Drug Safety 309, 310 (2009), filed as Exhibit G (ECF No. 39-7). Moreover, *C. jejuni* infections were *specifically* associated with the AMAN GBS variant. Pei Shang et al., *Axonal Variants of Guillain-Barré Syndrome: An Update*, 268 J. Neurol. 2402, 2403 (2021), filed as Exhibit H (ECF No. 39-8). Here, the record established that Petitioner had experienced some kind of gastrointestinal illness prior to neurologic symptoms onset—and hence it was likely that a *C. jejuni* infection had caused those initial symptoms.

The timing of that infectious process also cast into doubt the vaccine's causality. The medical record clearly established that Petitioner's gastrointestinal symptoms began several days prior to vaccination, and Dr. Bromberg interpreted the record to pinpoint an onset for such symptoms as October 26-27, 2016. First Bromberg Rep. at 8. The record allowed for some possibility of GBS onset pre-vaccination, however, since Petitioner had (at the time of his initial ED visit) suggested in his medical history that he had been experiencing comparable numbness and weakness for a week—or before the November 1st vaccination. *Id.* In fact, Petitioner complained of leg weakness at the same visit he obtained the vaccine. *Id.* The flu vaccine could not be causal of Petitioner's AMAN if it began before vaccination.

Moreover, record evidence of initial, post-vaccination symptoms revealed they had occurred too close in time to the vaccine's administration to suggest the timeframe was medically acceptable. As Dr. Bromberg noted, ED medical records, plus records from Petitioner's visits to Dr. Trevino later, supported an onset of either immediately after vaccination, or by November 3rd at the latest (two days post-vaccination). First Bromberg Rep. at 8. Any such timeframe would be inconsistent with vaccine causality, since the theory by which GBS was thought to occur post-vaccination relied on molecular mimicry between the vaccine's presenting antigens and self

structures. *Id;* Haber at 312. But the autoimmune cross-reactive process that would cause nerve damage would be mediated by the *adaptive* immune response—"and this process, if vaccine-induced, likely takes longer than 48 hours to result in clinical symptoms." First Bromberg Rep. at 8. A two-day onset was certainly incompatible with the flu vaccine-GBS Table claim, which required onset to occur no sooner than three days post-vaccination. *Id.*

At the same time, Dr. Bromberg opined, Petitioner's neurologic symptoms onset was consistent with the timeframe for GBS caused by a *C. jejuni* infection. Assuming an onset of the infection in late October, neurologic symptoms manifesting approximately a week or more from infection (early November) was wholly consistent with the medical science on the subject. First Bromberg Rep. at 8; J.H. Rees et al., *Campylobacter Jejuni Infection and Guillain-Barré Syndrome*, 333 N. Engl. J. Med. 1374, 1376 (1995), filed as Exhibit I (ECF No. 39-9) ("Rees") (mean interval of nine days from diarrhea to neuropathic symptoms, with range of two to 20 days); Richard A.C. Hughes and Jeremy H. Rees, *Clinical and Epidemiological Features of Guillain-Barre´ Syndrome*, 176 J. Infect. Dis. 92, 95 (1997), filed as Exhibit J (ECF No. 39-10) (range of 5 to 21 days).

Dr. Bromberg concluded by briefly disputing some of the points Drs. Trevino and Sanchez had made in their affidavits. Regarding Dr. Trevino's argument about antibiotic treatment eliminating the presence of *C. jejuni,* Dr. Bromberg noted the distinction between "when the bacterium is active and pathogenic," prior to the antibiotic's effectiveness, and the date of onset of neurologic symptoms. First Bromberg Rep. at 9. And the impact of antibiotic treatment would "not cause the protein components [of the bacterium] to disappear," thus allowing the possibility for a molecular mimicry-mediated autoimmune response later. *Id.* In addition, Dr. Bromberg expressed the view that regardless of Petitioner's 2021 gallbladder removal (and the suggestion that this revealed Petitioner had possibly been suffering from some form of gallbladder disease), the records were not consistent with the conclusion that this was Petitioner's ailment in 2016 (over four years before). *Id.* And Dr. Bromberg could not find independent evidence associating the diarrheal symptoms Petitioner had first complained of in late October 2016 and cholecystitis. *Id.*

Second Report

The next report offered from Dr. Bromberg commented upon Dr. Simpson's first report. Regarding diagnosis, Dr. Bromberg agreed that Petitioner's electrodiagnostic study results confirmed the presence of *some* form of peripheral neuropathy, despite the issues he had identified with how the testing had been conducted. Second Bromberg Rep. at 1. But he did not accept that the AIDP[8] form of GBS was confirmed by this testing. *Id.* He also opined that the results might

[8] Acute inflammatory demyelinating polyneuropathy, the most common subtype of GBS. T. Adnan Alam et al., *Electrophysiological Studies in the Guillain–Barré Syndrome: Distinguishing Subtypes by Published Criteria*, 21 Muscle & Nerve 1275, 1279 (1998), filed as Exhibit M (ECF No. 59-2).

have been complicated by Petitioner's medical history of diabetes. That history could produce a neuropathy similar to what Petitioner had experienced—and the testing results were as consistent with that cause as others. *Id.*

Relatedly, Dr. Bromberg took note of the fact that this testing occurred within approximately one month of vaccination—meaning that the impact and effect of whatever had caused Petitioner's GBS or comparable symptoms should then have been manifest. Second Bromberg Rep. at 1. Although the results of the testing revealed a "moderately severe" form of neuropathy, findings associated with the needle EMG study remained inconsistent, and were not all that reflective of an "axonal polyneuropathy." *Id.* at 2. Dr. Bromberg therefore (and somewhat inconsistent with his first report) now proposed that the EMG findings from the December 2016 testing should be "set aside," leaving NCS results only consistent with a diabetic neuropathy. *Id.* (He nevertheless thereafter assumed Petitioner could have been properly diagnosed with AMAN).

On the issue of causation, Dr. Bromberg disputed Dr. Simpson's contention that Petitioner's gastroenteritis could have a viral cause (in which case the *C. jejuni*-GBS association would have no bearing on cause in this case). Second Bromberg Rep. at 2. He emphasized that the first physician to treat Petitioner for his late-October 2016 symptoms, Dr. Trevino, had seemed to accept a bacterial cause for the symptoms, since he prescribed anti-bacterial medication (which would be ineffective in treating a viral infection). *Id. C. jejuni* was widely understood in the medical community *both* to cause gastroenteritis, but also to be associated with AMAN (the only GBS variant that might be applicable to Petitioner). *Id.* (By contrast, what existing literature associated GBS with the flu vaccine seemed mostly to involve AIDP, rather than AMAN). A. Shaikh et al., *Atypical Forms of Guillain-Barré Syndrome and H1N1-influenza Vaccination*, 30 Vaccine 3251, 3254 (2012).[9] The record evidence overall, Dr. Bromberg opined, was mostly consistent with a bacterial infectious cause for Petitioner's neuropathy (to the extent it was not a "metabolic neuropathy" that would be attributable to Petitioner's preexisting diabetes—a conclusion Dr. Bromberg seemed to find more credible). Second Bromberg Rep. at 3.

Third Report

Dr. Bromberg's final filing was a two-page response to Dr. Simpson's second written report. He again agreed that the electrodiagnostic testing confirmed the presence of a peripheral neuropathy, but that distinctions in the NCS findings for arms versus legs were "unusual," despite Dr. Simpson's contentions that asymmetry in GBS was not unheard-of. Third Bromberg Rep. at 1. He also made some specific comments about the extent to which the "sural sparing pattern" was as specific for GBS as Dr. Simpson maintained, noting that certain studies found it associated with diabetic neuropathies as well. M. Bromberg and J. Albers, *Patterns of Sensory Nerve Conduction*

[9] Respondent has not filed this article, thus there is no record citation.

Abnormalities in Demyelinating and Axonal Peripheral Nerve Disorders, 16 Muscle & Nerve 262, 265 (1993), filed as Exhibit N (ECF No. 59-3).

Dr. Bromberg otherwise repeated the view that the "quality of information" in Petitioner's electrodiagnostic testing was questionable, making it difficult to place great weight on the findings. Third Bromberg Rep. at 3. And he contended that the mechanistic models proposed in this case for how the flu vaccine could cause GBS could not overcome the plain fact that (a) neuropathies post-vaccination were uncommon, whereas (b) they often occur in the absence of vaccination. *Id.*

III. Procedural History

The Petition was filed a little more than four years ago, and initially assigned to SPU, since claims that the flu vaccine caused GBS are common in the Program (and more often than not asserted as a Table claim). However, in June 2021 I ordered Petitioner to show cause why the claim should not be dismissed, given both the evidence of the preexisting gastrointestinal infection as a potential alternative explanation for Petitioner's GBS, as well as the fact that the medical records strongly suggested an onset too rapid to meet the Table's three-day onset period. *See* Order to Show Cause, dated June 9, 2021 (ECF No. 31).[10]

Thereafter, however, Petitioner offered the treater statements discussed above, and noted that fact issues existed as to the alternative cause question as well as onset. Scheduling Order, dated July 27, 2021 (ECF No. 35). I accordingly ordered Respondent to offer expert support for his position, and he did so with the filing of Dr. Bromberg's first report in November 2021. Petitioner responded with reports from Dr. Simpson, and in the course of this process I transferred the matter out of SPU to my individual docket for final resolution. I set a briefing schedule for a ruling on the record in the beginning of 2023, the parties made their written submissions, and the matter is now ripe for resolution.

IV. Parties' Arguments

Petitioner

Mr. Velasquez maintains he has met all elements for a causation-in-fact claim. He notes that the "can cause" prong is easily met, since the flu vaccine-GBS association is well-established (citing a prior decision of my own in support), and noting Dr. Simpson's evidentiary showing on the subject. Mot. at 4–5. He also argues that the second, "did cause" prong has preponderant support. *Id.* at 5. He observes that Petitioner's contemporaneous treaters (in particular Drs. Trevino and Sanchez) concur that the vaccine was causal in this case, over other alternative explanations

[10] As Chief Special Master, all SPU cases are assigned to me, although they grouped separately from the non-SPU cases on my docket.

that the record reveals, such as a *C. jejuni* infection or diabetes-related neuropathy. *Id.* at 5–7, 9–10. Petitioner had no symptoms pre-vaccination, and Dr. Bromberg's proposed alternative causes lack preponderant support.

A larger portion of this brief is devoted to Petitioner's efforts to bulwark the evidence that the onset of his GBS occurred in a medically-acceptable timeframe, measured from the date of vaccination. In so doing, he deems his onset to have occurred "2-3 days after vaccination"— hence outside the Table claim's 3-42 day timeframe (although he goes to some effort to rebut the contention that his GBS was evident *at the time* of vaccination, if not before, and also emphasizes evidence consistent with the Table timeframe). Mot. at 6, 11–13. But he nevertheless argues (relying on Dr. Simpson) that the shorter onset timeframe he likely experienced was medically acceptable, representing that regardless of the Table claim elements, the actual, scientifically-accepted timeframe is *both* shorter and longer. *Id.* at 6, 11. Petitioner also contends that his onset timeframe was inconsistent with the theory that his GBS was caused by a *C. jejuni* bacterial infection, noting that both Drs. Trevino and Sanchez offered medical literature establishing that the lag from infection to onset would be no less than ten days, and hence longer than what Petitioner experienced. *Id.* at 8.

Respondent

Respondent argues for the claim's dismissal, placing greatest emphasis on the timeframe prong as not preponderantly supported. Opp. at 9–13. He notes record evidence suggesting onset occurred as early as the day of vaccination (since Petitioner complained that day of back pain and leg weakness, which logically would have begun *before* the November 1st visit to Dr. Trevino). *Id.* at 9–10. He later reported onsets that would have begun pre-vaccination, if not the day of. *Id.* at 10. And he disputed arguments that these symptoms were non-neurologic (for example, lower back disc issues) as lacking record support, while also maintaining that the records generally merited more weight than Petitioner allowed. *Id.* at 11–12.

Respondent offered other arguments about the timeframe of onset in this case. He rejected Petitioner's claim that GBS caused by gastroenteritis (in the wake of a *C. jejuni* infection) would involve a longer onset timeframe, contending that in fact (assuming an onset of the bacterial infection predated vaccination), Petitioner's neurologic symptoms would have begun about a week after *regardless* of cause—consistent with Petitioner's own literature offered on the subject. Opp. at 16–17. In fact, Dr. Bromberg had cited literature supporting onset of GBS in that timeframe after such an infection. *Id.* at 17; Rees at 3. Petitioner's argument that a vaccine-induced GBS would occur in a shorter timeframe was wholly inconsistent with medical and scientific understanding of how long it would take *any* autoimmune disease mediated by molecular mimicry (vaccine or infection) to manifest symptoms—since medical science understands that a *C. jejuni*-caused form of GBS will be mediate by molecular mimicry as well. *Id.* at 18. A too-short timeframe

for a molecular mimicry-mediated disease had often resulted in a claim's dismissal. *Id.* at 20–21 (citing cases in which one-day timeframe was adjudged to be too short).

Otherwise, Respondent reasoned that the second causation prong could not be met.[11] Strong evidence suggested, for example, that Petitioner's GBS was associated with a gastroenteritis infection he had experienced slightly prior to vaccination. Opp. at 14–15. Indeed, the form of GBS he likely had experienced, AMAN, is "highly associated" with a *C. jejuni* infection (which might in turn explain Petitioner's initial gastrointestinal symptoms). *Id.* at 15. The fact that it could not be shown with certainty that Petitioner had experienced such an infection was no matter, since controlling Circuit law does not require such precise causal identification. *Id.* at 15–16; *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994) ("[t]here is nothing in the Vaccine Act that requires a per se rule that alternative causation cannot be proved when the specific virus is not identified.").

V. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[12] Although this matter was initially designated for the SPU (since claims that the flu vaccine can cause GBS are common in the Program, and hence frequently can be resolved in short order), Petitioner does not assert a flu-vaccine/GBS Table claim (given his tacit acknowledgment that onset occurred outside the Table's defined timeframe).

Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture

[11] Respondent also challenges the adequacy of Petitioner's prong one showing, but for reasons discussed below, I need not evaluate Petitioner's success on that topic in resolving the claim.

[12] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274 , 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of

proof" (citing *Moberly*, 592 F.3d at 1322)); *Howard v. Sec'y of Health & Hum. Servs*., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *appeal docketed*, No. 23-1816 (Fed. Cir. Apr. 28, 2023). Otherwise, petitioners *always* have the ultimate burden of establishing their Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical

understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for*

review den'd, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Standards for Ruling on the Record*

I am resolving Petitioner's claim on the filed record, and the parties have not challenged my determination to do so. Mot. at 1. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Petitioner Has Not Met His Prima Facie Burden of Proof

Petitioner has not alleged a Table claim in this case. In fact (and despite Dr. Simpson's representations of a three-day onset as supported by the record) he *could not* successfully maintain one. The medical records preponderantly establish that onset occurred *less than* three days after vaccination—thus sooner than the timeframe provided for by the Vaccine Injury Table. 42 C.F.R. § 100.3. And Petitioner does seem to accept that the evidence preponderates in this direction. Mot. at 21 ("the vast majority of the references place the onset of symptoms after the flu vaccine, with most stating *2-3 days after vaccination*" (emphasis added)).

Petitioner nevertheless argues that he can establish causation under the three prongs set by the Federal Circuit in *Althen*. But I cannot agree the record supports the claim. Resolution of this matter primarily turns on the third and second *Althen* prongs (and I address them in that order, given their relative importance).[13]

First, the timeframe prong has not been satisfied. Petitioners seeking to prove GBS was caused by the flu vaccine on a "non-Table" basis, as here, are of course not formally limited by the Table's 3-42 day onset period. Nevertheless, this timeframe *best captures* the most likely period in which vaccine-caused GBS would begin, based on the most persuasive and reliable science. *See Rowan v. Sec'y of Health & Hum. Servs.*, No. 17-760V, 2020 WL 2954954, at *14–16 (Fed. Cl. Spec. Mstr. Apr. 28, 2020) (discussion of the relationship between Table requirements and non-Table claims in context of flu-GBS claims).

Thus, petitioners seeking to prove a medically acceptable timeframe for flu vaccine-caused GBS as shorter than three days post-vaccination have their work cut out for them. Only where other factors suggest some synergistic combination of causes has a flu vaccine been deemed a "substantial factor" in producing GBS so rapidly—but in most cases this cannot be accomplished. *See*, e.g., *Orton v. Sec'y of Health & Hum. Servs.*, No. 13-631V, 2015 WL 1275459 (Fed. Spec. Mstr. Cl. Feb. 23, 2015) (dismissing claim where inadequate evidence established the medical

[13] There is little dispute in the Vaccine Program that the flu vaccine "can cause" GBS, and hence I deem the first *Althen* prong satisfied (although that is not enough to save the claim, since *all three* prongs must be met for entitlement to be found). Respondent raised some fair points against that conclusion, but I am reluctant to give them significant weight—for the same policy reasons I am unpersuaded by Dr. Simpson's efforts to "stretch" the timeframe set by the Table for onset. Although it is often the case in the Vaccine Program that failed Table claims are deemed potentially viable as causation-in-fact claims, special masters should not disregard the science that led the Government to adopt the contours of the comparable Table claim in the first place. By allowing a Table claim, the Government is giving weight to the scientific evidence supporting the conclusion that the flu vaccine might be causal of GBS in some cases. That determination is not appropriately disregarded or ignored simply because other aspects of the Table claim cannot be met.

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acceptability of a one-day onset of GBS); *Rowan*, 2020 WL 2954954, at *19 (dismissing claim because it did not demonstrate 30-36 hour onset in elderly petitioner). They cannot prevail simply by making the blanket assertion (as Dr. Simpson does) that the 3-42 day period is *itself* imprecise or too limited. This amounts to asking the special master to create a "side Table," in which longer or shorter onsets are deemed as medically acceptable as what already exists, but without any showing specific to the claimant's circumstances that would justify stretching the Table timeframe.

Accordingly, Petitioner needed to offer persuasive and reliable evidence for why in this case a shorter onset would make medical "sense." Dr. Simpson's opinion does not accomplish this. Petitioner's experts instead seemed to embrace the idea that the timeframe for an infectious cause of GBS (such as via *C. jejuni*) would inherently be *longer* than a few days, ruling out that infection as causal. *See,* e.g., Sanchez Rep. at 2.

But what is it about the nature of vaccination supporting the conclusion that causation could occur in *even less* time than a wild infection?[14] This is an unanswered question—and one that is not even well-founded, given that vaccines are engineered to promote a controlled immune response less harmful than what a live viral or bacterial infection would cause. Indeed, the flu vaccine at issue is not adjuvanted—it does not contain alum or some comparable agent intended to boost the immune response. *Dougherty v. Sec'y of Health & Hum. Servs.*, No. 15-1333V, 2018 WL 3989519, at *14 (Fed. Cl. Spec. Mstr. July 5, 2018), *aff'd*, 2018 WL 7022203 (Fed. Cl. Dec. 28, 2018) (all expert witnesses agreeing that no flu vaccines administered in the US contain adjuvants). Thus, the immune response it triggers will, inherently, be *even less robust* than vaccines containing an adjuvant—reducing the power of the response, and perhaps in some cases *even slowing* the immune reaction. I have noted in comparable cases that this is why different versions of the flu vaccine are administered to certain populations (in particularly, the elderly): to make up for the fact that the straightforward, inactivated formulation lacks sufficient immunogenicity for those groups. *Rowan*, 2020 WL 2954954, at 7.

Otherwise, the articles filed in this case do not establish an onset of less than three days is likely, as I have noted in other matters. *See,* e.g., *Rowan,* 2020 WL 2954954, at 16 (discussion of Schonberger's applicability to vaccine injury claims). Certainly these articles do not support the conclusion that vaccine-caused GBS will occur in a faster timeframe than a wild infection.

Also relevant to my determination is the manner in which infections (and some vaccines) are thought to cause GBS. The proposed mechanism by which the flu vaccine (or bacterial infections like *C. jejuni*) can cause an autoimmune-mediated peripheral neuropathy, molecular

[14] In fact, an onset closer-in-time to vaccination in this case is *more supportive* of an infection (bacterial or viral) as causal. The medical record clearly establishes that Petitioner's gastrointestinal symptoms *predated* vaccination – and so any autoimmune-mediated process had even longer to begin (when measuring from Petitioner's first symptoms manifestation) than what the vaccine could have caused.

mimicry, involves an adaptive immune response that more often than not is expected to take well *more* than three days to occur. *Forrest v. Sec'y of Health & Hum. Servs*, No. 14-1046V, 2019 WL 925495, at *6 (Fed. Cl. Spec. Mstr. Jan. 28, 2019) (detailed discussion of timeframe for molecular mimicry, and production of antibodies in reaction to a vaccine's antigens). No other persuasive evidence was offered suggesting it is otherwise for the flu vaccine. And I have in other cases noted that articles like Park reveal only that another country's vaccine compensation program *paid* damages in cases of short onset, with no discussion of whether such an onset had scientific or medical support. *See,* e.g., *Block v. Sec'y of Health & Hum. Servs.*, No. 19-969V, 2021 WL 2182730, at *5, 8–9 (Fed. Cl. Spec. Mstr. Apr. 26, 2021) (dismissing flu-GBS Table claim due to onset occurring outside the defined 3-42 day timeframe, and discussing Korean vaccine injury program referenced in Park).[15] This is hardly robust proof that a short onset is medically acceptable.

At bottom, numerous decisions in the Program have ruled that in cases alleging molecular mimicry as the immune-mediated mechanism for disease, an onset of less than three days is too short to find the vaccine causal. *See* Opp. at 20 (list of cases in which claims of one-day onset were rejected).

The second, "did cause" prong is also unsatisfied. There is no evidence of any suspicious vaccine reaction that could suggest an aberrant immune response had begun. No testing or clinical observations make causation by vaccine likely. And there is some, admittedly equivocal, evidence that Petitioner's post-vaccination neuropathic symptoms may have reflected complaints about pain and leg weakness he was not only experiencing before November 1st, but *the same day* as vaccination. Ex. 2 at 16. (This kind of evidence also suggests the possibility of a pre-vaccination onset,[16] although I have found the record preponderates otherwise).

By contrast, although contemporaneous treaters like Drs. Trevino and Sanchez do opine that the vaccine was causal, their opinions are either conclusory in nature (especially so for Dr. Sanchez) or over-rely on a purported distinction for the timeframe of infection-caused GBS versus vaccine-caused that lacks reliable scientific support. And I am not otherwise obligated to accept their opinions at face value merely because they treated Petitioner, but may weigh them against not only contrary evidence, but their own internal reliability. *Snyder v. Sec'y of Health & Hum. Servs.*, No. 01-162V, 2009 WL 2569773 at n.67 (Fed. Cl. Spec. Mstr. Aug. 11, 2009) ("[h]owever, there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). Here, these opinions are not especially probative of causation.

[15] *Block* also involved an expert opinion from Dr. Simpson. *Block*, 2021 WL 2182730, at *5.

[16] *See,* e.g., Ex. 3 at 9 (reporting onset at ED or symptoms beginning a week before the November 4, 2016 treatment visit).

Another issue with establishing the flu vaccine caused Petitioner's GBS is the ample evidence of an alternative explanation for his injury: the gastrointestinal infection. Although Program claimants are never obligated to "rule out" alternative explanations for an injury, evidence of competing explanations (especially when self-evident from the medical record—as here) is highly relevant to evaluation of the "did cause" prong. Too much evidence of such explanations can often fairly undermine a claimant's evidentiary showing. *See Winkler v. Sec'y of Health & Hum. Servs.*, 88 F.4th 958 (Fed. Cir. 2023).

Here, it is incontrovertible that Petitioner had a number of preexisting comorbidities that could cause neuropathic symptoms, like diabetes—and that were not well-controlled at the time of vaccination. *See,* e.g., Ex. 2 at 14, 16. On top of that, Petitioner had been treated in the days before vaccination for gastroenteritis. *Id.* at 19. He received antibiotics for it, suggesting the view (at least at the time) that its cause was bacterial—and there is a well-known association between a specific kind of bacterial infection, *C. jejuni*, and the AMAN form of GBS Petitioner likely experienced. *See* Opp. at 15.

It is true, as Petitioner notes, that the precise nature of the GI infection was never identified (although as already noted such a competing causal factor need not be proven for the mere fact of the ailment to undermine causation). *Knudsen,* 35 F.3d at 549. It could have been viral (though that would not prevent the determination that it caused Petitioner's GBS). And the infection is not necessarily *C. jejuni* simply because Petitioner's form of GBS was AMAN. More compelling is Petitioner's contention (primarily advanced by Dr. Trevino) that in retrospect these symptoms could have been misconstrued, and might instead have reflected a gallbladder issue that was at the time not known.

All of these competing factors somewhat reduce the strength of Respondent's rebuttal of the second prong—although there is enough evidence in the record on this point to find that Petitioner has not preponderantly shown that the flu vaccine *Petitioner* received likely played a substantial role in his GBS. And even if he had met his burden on this single prong, the established, too-fast onset would remain a primary basis for denying entitlement—since that question was *not* preponderantly established in Petitioner's favor to any degree.

CONCLUSION

A Program entitlement award is only appropriate for claims supported by preponderant evidence. Here, Petitioner has not made such a showing. Petitioner is therefore not entitled to compensation.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[17]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[17] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.